

DISPOSITION: 2-26-58. Default—destruction.

5721. Arben capsules. (F.D.C. No. 40615. S. No. 65-351 M.)

INFORMATION FILED: 8-4-58, S. Dist. Fla., against Arthur Bennett, Miami Beach, Fla.

SHIPPED: 12-31-56, from Miami Beach, Fla., to Youngstown, Ohio.

LABEL IN PART: "Arben Capsules Number 2 Each capsule contains: Desiccated Thyroid 5 mgm. Caffeine 2.2 mgm. Amphetamine Sulfate 1.2 mgm. With fillers Arthur Bennett Pharmaceuticals Miami Beach, Florida #1109."

CHARGE: 501(c)—the strength of the article differed from that which it purported to possess since each capsule of the article contained more than 1.2 milligrams of amphetamine sulfate.

PLEA: Nolo contendere.

DISPOSITION: 2-25-59. \$1,000 fine.

5722. Del-Bardex capsules. (F.D.C. No. 41692. S. No. 39-322 P.)

QUANTITY: 1 drum containing 9,600 capsules at Napa, Calif.

SHIPPED: 3-12-58, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABEL IN PART: "Del-Bardex #1 Timed Disintegration Capsule Each Capsule Contains: Dextro Amphetamine Sulfate 10 mg. Amobarbital 60 Mg. * * * Each Capsule Contains 15 Mg. of Dextro Amphetamine Sulfate and 60 Mg. of Amobarbital In a Special Base That Provides for the Disintegration of the Contents Throughout a Period of About 6-10 Hours."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 10 milligrams of dextro-amphetamine sulfate of which 70 percent was released in 2 hours.

LABELED: 5-6-58, N. Dist. Calif.

CHARGE: 501(c)—the quality of the article, when shipped, differed from that which it purported or was represented to possess in that it failed to disintegrate at a uniform rate over a 6-10 hour period; and 502(a)—the label statement "Each Capsule Contains 15 Mg. of Dextro Amphetamine Sulfate * * * In a Special Base That Provides for the Disintegration of the Contents Throughout a Period of About 6-10 Hours" was false and misleading as applied to the article which contained only 10 milligrams of dextro-amphetamine sulfate per capsule, and did not release such ingredient at a uniform rate over a 6-10 hour period.

DISPOSITION: 6-12-58. Default—destruction.

5723. Somnesium capsules. (F.D.C. No. 41861. S. No. 31-358 P.)

QUANTITY: 326 24-capsule vials at Newark, N.J., in possession of Hicks Pharmacal Co.

SHIPPED: 9-25-57, from Mount Vernon, N.Y.

LABEL IN PART: "Somnesium to induce Sleep Each capsule contains 25 mg. Methapyrilene HCl. 66.6 mg. Aspirin 133.4 mg. Salicylamide * * * Distributed by Hicks Pharmacal Company."

RESULTS OF INVESTIGATION: Examination showed that the product had the odor of acetic acid, a caking of the contents, free salicylic acid, and 70 percent of the labeled amount of aspirin, all of which indicated decomposition of the aspirin. The article contained the labeled amount of methapyrilene HCl and salicylamide.

The article was repacked locally for the dealer from bulk stock shipped as described above.

LIBELED: 6-11-58, Dist. N.J.

CHARGE: 501(c)—while held for sale, the strength of the article differed from, and its purity and quality fell below, that which it purported and was represented to possess; and 502(a)—the label statement "Each capsule contains * * * 66.6 mg. Aspirin" was false and misleading.

DISPOSITION: 7-14-58. Default—destruction.

5724. Nibromiphen tablets. (F.D.C. No. 41886. S. No. 8-968 P.)

QUANTITY: 3 bulk drums, each containing 31,600 tablets, and 1 btl. containing 1,000 tablets at Rochester, N.Y., in possession of Groh Co.

SHIPPED: 11-11-54, from Cleveland, Ohio.

LABEL IN PART: (Drum) "Special Tablets Lt. Blue Enteric." and (btl.) "Nibromiphen Enteric Coated Tablets."

RESULTS OF INVESTIGATION: The tablets in the bottle had been repackaged by the consignee from the above-described bulk drums.

LIBELED: 6-25-58, W. Dist. N.Y.

CHARGE: 501(c)—while held for sale, the quality of the article fell below that which it purported and was represented to possess since it was represented as enteric-coated tablets, and the enteric coating was split and falling off, and the tablets were discolored and stuck together in clumps.

DISPOSITION: 8-1-58. Default—destruction.

5725. Sulfobromophthalein sodium injection. (F.D.C. No. 41775. S. Nos. 15-405 P, 16-416 P.)

QUANTITY: 5 ctns. containing a total of 435 ampules at Toledo, Ohio.

SHIPPED: 2-14-58, from New York, N.Y., by Vitarine Co., Inc.

LABEL IN PART: (Ampule) "3 cc. No. 692 Sulfobromophthalein Sodium Injection U.S.P. 50 mg. Per cc. Intravenous Control No. 7566."

RESULTS OF INVESTIGATION: Examination showed that the article contained an excessive amount of pyrogen and failed to comply with the pyrogen test of the United States Pharmacopeia.

LIBELED: 5-23-58, N. Dist. Ohio.

CHARGE: 501(b)—the article purported to be a drug, sulfobromophthalein, the name of which is recognized in the United States Pharmacopeia, an official compendium, and, when shipped, its quality and purity fell below that required by the Pharmacopeia.

DISPOSITION: 8-21-58. Default—destruction.

5726. Beef, iron, and wine preparation. (F.D.C. No. 42073. S. No. 38-403 P.)

QUANTITY: 56 btls. at Texarkana, Ark.

SHIPPED: 2-4-58, from St. Louis, Mo., by Allan & Co.

LABEL IN PART: "One Pint Allan's Beef, Iron and Wine."

RESULTS OF INVESTIGATION: Examination showed that the article contained significantly less iron and ammonium citrate than the amount specified in the National Formulary for "Beef, Iron and Wine."

LIBELED: 8-1-58, W. Dist. Ark.